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| APPLICATION NO.                    | FILING DATE   | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
|------------------------------------|---------------|----------------------|-------------------------|------------------|--|
| 09/699,923 10/30/2000              |               | David H. Lynch       | 2836-Е                  | 8828             |  |
| 75                                 | 90 02/25/2002 |                      |                         |                  |  |
| Kathleen Fowler                    |               |                      | EXAMINER                |                  |  |
| Immunex Corporation Law Department |               |                      | GAMBEL, PHILLIP         |                  |  |
| 51 University Street               |               |                      | ART UNIT                | PAPER NUMBER     |  |
| Seattle, WA 98                     | 8101          |                      | ART ONT                 |                  |  |
|                                    |               |                      | 1644                    | 9                |  |
| DATE MA                            |               |                      | DATE MAILED: 02/25/2002 |                  |  |

Please find below and/or attached an Office communication concerning this application or proceeding.



## UNITED STATE EPARTMENT OF COMMERCE Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

FILING DATE

FIRST NAMED APPLICANT

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|---|----------|--------------|
|   | EXAM     | INER         |
|   | ART UNIT | PAPER NUMBER |
|   | 1644     | 9            |

DATE MAILED:

This is a communication from the examiner in charge of your application.

|     | COMMISSIONER OF PATENTS AND TRADEMARKS  |                    |   |  |  |  |  |  |
|-----|---|--------------------|---|--|--|--|--|--|
|     | OFFICE ACTION SUMM  | IARY               |   |  |  |  |  |  |
| ₫   | Responsive to communication(s) filed on   |                    |   |  |  |  |  |  |
|     | This action is FINAL.   |                    |   | •  |  |  |  |  |
|     | Since this application is in condition for allowance except for formal matters, accordance with the practice under <i>Ex parte Quayle</i> , 1935 D.C. 11; 453 O.G.  | prosecution as:    | to the merits is clo  | osed in                                      |  |  |  |  |
| the | hortened statutory period for response to this action is set to expire  | and within the per | _ month(s), or thirty<br>riod for response wi<br>der the provisions o | days,<br>ill cause<br>of 37 CFR              |  |  |  |  |
| Dis | position of Claims  | •                  |   |  |  |  |  |  |
|     | Claim(s) 12,13,11-36  |                    | is/are pending i  | n the application.                           |  |  |  |  |
| _   | Claim(s) 12,13,11-36 Of the above, claim(s)   |                    | is/are withdrawn from consideration.                                  |  |  |  |  |  |
| 믬   | Claim(s)  |                    | is/a  | are allowed.                                 |  |  |  |  |
|     | Claim(s)  |                    | is/are  | are rejected.<br>objected to.                |  |  |  |  |
| Ø   | Claim(s)  | are subject        | to restriction or ele-  | ction requirement.                           |  |  |  |  |
| Ąр  | plication Papers  |                    |   |  |  |  |  |  |
|     | See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  The drawing(s) filed onis/at The proposed drawing correction, filed on The specification is objected to by the Examiner. The oath or declaration is objected to by the Examiner. | re objected to by  | the Examiner. s  approved   | ] disapproved.                               |  |  |  |  |
| Pri | ority under 35 U.S.C. § 119   |                    |   |  |  |  |  |  |
|     | Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 118  | 9(a)-(d).          | •   |  |  |  |  |  |
|     | All Some* None of the CERTIFIED copies of the priority doc  | cuments have bee   | эп  |  |  |  |  |  |
|     | received.   |                    | •   |  |  |  |  |  |
|     | received in Application No. (Series Code/Serial Number) received in this national stage application from the International Bureau   | (PCT Rule 17.2(    | <br>a)).  |  |  |  |  |  |
|     | *Certified copies not received:   |                    |   | <u>.                                    </u> |  |  |  |  |
|     | Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §   | 119(e).            |   |  |  |  |  |  |
| At  | tachment(s)   |                    | •   |  |  |  |  |  |
|     | Notice of Reference Cited, PTO-892  |                    |   |  |  |  |  |  |
|     | Information Disclosure Statement(s), PTO-1449, Paper No(s).   |                    |   |  |  |  |  |  |
|     | Interview Summary, PTO-413  | •                  |   |  |  |  |  |  |
|     | Notice of Draftperson's Patent Drawing Review, PTO-948  |                    |   |  |  |  |  |  |
| _   | Notice of Informal Patent Application, PTO-152  |                    |   |  |  |  |  |  |

Serial No. 09/699923 Art Unit 1644

## **DETAILED ACTION**

1. Applicant's amendment, filed 10/30/00 (Paper No. 6), has been entered.

Claims 1-11 and 14 have been canceled.

Claims 12-13 have been amended.

Claims 15-36 have been added.

- 2. Applicant's election of the species GM-CSF in Paper No. 8, filed 12/7/01, is acknowledged.
- 3. Upon reconsideration of the claims, it is noted that independent claim 12 is drawn to transfecting dendritic cells with a gene encoding an antigen while independent claim 15 is drawn to exposing dendritic cells with an antigen. Given that the claims encompass different method steps and ingredients encompassed by such methods, the following Restriction is set forth. The examiner apologizes to applicant for any inconvenience in this matter.
- 4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:
- I. Claims 12-13, 17-22, drawn to a method of preparing antigen-presenting dendritic cells by transfecting said dendritic cells with a gene encoding an antigen, classified in Class 435, subclasses 375 and 455.
- II. Claims 15-16, 23-36, drawn to a method of preparing antigen-presenting dendritic cells, classified in Class 435, subclasses 2 and 377.
- 5. Inventions I and II are different methods, which require different ingredients, process steps and endpoints. Therefore, they are patentably distinct.
- 6. Applicant's election of GM-CSF is acknowledged.

This application contains claims directed to the following patentably distinct species of the claimed Groups I and II: wherein the molecule in addition to flt3-ligand is:

- A) GM-CSF.
- B) IL-4,
- C) TNF-α,
- D) IL-3,
- E) c-kit ligand,
- F) fusions or GM-CSF and IL-3.
- G) CD40L or
- H) CD40-specific antibody.

These species are distinct because their structures and modes of action are different.

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Applicant is required under 35 U.S.C. § 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 12, 15 and 29 are generic.

7. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

- 8. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.
- 9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).
- 10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phillip Gambel whose telephone number is (703) 308-3997. The examiner can normally be reached Monday through Thursday from 7:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

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Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center telephone number is (703) 305-3014.

PHILLIP GAMORE

Phillip Gambel, PhD. Primary Examiner Technology Center 1600 February 25, 2002